

SEP 11 2000

Attachment I
510(K) Summary
ProLite VL Pulsed Light System

K002072

This 510(K) Summary of safety and effectiveness for the ProLite VL Pulsed Light System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Medical Bio Care Sweden AB.
Address:	Lona Knapcs gata 5 421 32 Vastra Frolunda, Sweden
Contact Person:	Morgan Gustafsson
Telephone / Fax / Email	46.31.709.30.70 – Phone 46.31.709.30.79 – Fax morgan@medicalbiocare.com
Preparation Date:	04-01-2000
Device Trade Name:	ProLite VL Pulsed Light System
Common Name:	Pulsed Light for Photothermolysis
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device:	Photoderm VL System K number K950493
Description of the ProLite V Pulsed Light System	The ProLite V Pulsed Light System delivers pulsed light at a wavelength of 550 nanometers. The device consists of three interconnected sections: The cabinet which houses the power supply, the cooling system and the microcontroller, the umbilical to the handpiece, and the handpiece, which houses the waveguide
Intended use of the ProLite V Pulsed Light System	The ProLite VL Pulsed Light System is intended to be used for the treatment of shallow facial veins, telangiectasia, facial hemangiomas and rosacea vascular lesions.
Performance Data:	None
Conclusion:	The ProLite VL Pulsed Light System is substantially equivalent to other existing pulsed light systems in commercial distribution for treatment of vascular lesions in Dermatology and Plastic Surgery.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 11 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Medical BioCare Sweden AB
c/o Ms. Connie White Hoy
9630 Towner NE
Albuquerque, New Mexico 87112

Re: K002072
Trade Name: ProLite VL Pulsed Light System
Regulatory Class: II
Product Code: GEX
Dated: June 1, 2000
Received: July 7, 2000

Dear Ms. Hoy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

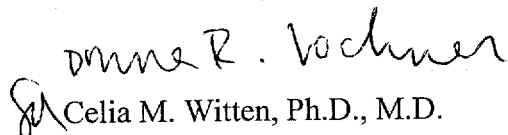
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT

510(k) Number: K0002072

Device Name: ProLite VL Pulsed Light System

Indications for Use:

The ProLite VL Pulsed Light System is intended to be used for the treatment of shallow facial veins, telangiectasia, facial hemangiomas and rosacea vascular lesions.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dennis R. Kochner.
Division Sign-Off
Division of General Restorative Devices
510(k) Number K002072

Prescription Use ☒
(per 21 CFR 801.109)

OR

Over-the-Counter Use ☐